

101



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,046	07/06/2001	Geert Maertens	2752-51	7316

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EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/899,046

Applicant(s)

MAERTENS ET AL.

Examiner

Tim Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This non-final Office action is responsive to the communication received June 3, 2004.

Applicant's election without traverse of Group I and SEQ ID NO:20 is acknowledged.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45-48 and 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to non-statutory because they read on a product of nature. The claims recite "[a]n HCV antibody specifically recognizing a type 3 HCV antigen . . . ." As such, the claims read on an antibody that is produced by the immune system of an HCV-infected individual. The claimed antibody is not isolated, or otherwise modified, such that it can be distinguished from an HCV antibody that occurs in nature. Thus, the claims are drawn to non-statutory subject matter.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 45 is indefinite because the language “[a]n HCV antibody specifically recognizing a type 3 HCV antigen . . .” does not clarify the scope of the claim. It is unclear whether “specifically recognizing . . . HCV antigen” refers to an (1) antibody that is specific for the claimed antigen, or (2) an antibody that is specifically recognizing (i.e. conjugated to) the claimed HCV antigen. Appropriate correction is required.

Claim 46 is indefinite in the recitation of “said antigen is consisting of . . . the region spanning positions 140 to 319 of Core/E1 of HCV type 3a identified by [SEQ ID NO: 20].” This language is indefinite because region 140 to 319 is longer than SEQ ID NO:20. Thus, it is unclear whether the claimed antigen is encoded by SEQ ID NO:20, or some other antigen having a length that corresponds with region 140 to 319.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 45-50 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. US 5,514,539 to Bukh et al. (“Bukh”).**

Bukh teaches an HCV antibody specifically recognizing a type 3 HCV antigen selected from the group consisting of an antigen of 5 or more continuous amino acids selected from the region spanning positions 140-319 of the Core/E1 region of HCV type 3a identified by SEQ ID

Art Unit: 1648

NO:20 (col. 7, lines 31-47), wherein the HCV antibody is produced by a mammal (Id. at lines 36-40), and wherein the antibody is a monoclonal antibody (col. 14, lines 12-40). Bukh further teaches humanizing the HCV antibody by means of recombinant DNA technology (col. 13, lines 9-21), and a composition comprising the antibody (col. 7, lines 31-47).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 51, 52 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. US 5,514,539 to Bukh et al. ("Bukh") in view of U.S. Pat. No. 5,350,671 to Houghten et al. ("Houghten").**

Bukh teaches Applicants' HCV type 3a antibody as noted above. Bukh does not expressly teach labeling this antibody with an enzymatic, fluorescent or radioactive label. However, Houghten teaches that HCV antigens can be detected in the serum of an infected individual using HCV antibodies that are labeled with an enzymatic, fluorescent, chemiluminescent or radioactive label (col. 36, lines 25-56). Therefore, at the time of Applicants' invention, it would have been obvious to modify Bukh with the teachings of Houghten in order to detect the antibodies that directed against Bukh's antigenic HCV peptide. This would be a desirable outcome since it would provide a means for confirming whether

Bukh's disclosed HCV vaccine is capable of producing an adaptive immune response in an immunized individual.

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown  
Examiner  
Art Unit 1648

tmb

  
JAMES HOUSEL 12/13/04  
SUPERVISORY PATENT EXAMINER  
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